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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,813	10/19/2004	Johannes Coy	4007.008	6538

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,813	COY, JOHANNES	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-39 and 41-64* is/are pending in the application.

4a) Of the above claim(s) *39,41-43 and 51-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-38 and 44-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 3/13/07 in response to the Office Action of 12/13/06 are acknowledged and have been entered.

Claims 34-39 and 41-64 are pending.

Claims 34, 37, 38, and 44-50 have been amended by Applicant.

Claims 39, 41-43, and 51-64 have been withdrawn.

Claims 34-38 and 44-50 are currently under examination.

The following Office Action contains NEW GROUNDS of rejections.

Objections Withdrawn

The objections cited in the Office Action of 12/12/06 are withdrawn.

Rejections Withdrawn

The rejections cited in the Office Action of 12/12/06 under 35 U.S.C. 112, second paragraph, are withdrawn.

Response to Arguments

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 34-38 and 44-50 under 35 U.S.C. 102(e), as being anticipated by Mack and Markowitz (US 2003/0235820 A1; filed 2/27/02), is maintained for the reasons found in the Office Action of 12/13/06 and for the reasons set-forth below.

The Office Action of 12/13/06 contains the following text:

"Mack and Markowitz teaches a method for detecting colon cancer comprising detecting the presence or absence and/or the level of expression of human transketolase like-1 polynucleotide in a cell or tissue sample from an individual and assessing diagnosis, wherein the presence of overexpression is indicative of colon cancer (see Table 17 and paragraphs 42-43, in particular). Mack and Markowitz further teaches a method of detecting the expression of human transketolase like-1 polynucleotide using a detectably labeled nucleic acid probe that hybridizes to a human transketolase like-1 polynucleotide (see paragraph 199, in particular), wherein the label is a radioisotope, a bioluminescent compound, a chemiluminescent compound, a fluorescent compound, or an enzyme (see paragraph 67, in particular). Mack and Markowitz further teaches a method of detecting the expression of human transketolase like-1 polynucleotide using a nucleic acid amplification reaction, wherein the amplification reaction is PCR or LCR (see paragraphs 143 and 198, in particular). Mack and Markowitz further teaches said hybridization methods can be performed in situ (see paragraph 205, in particular). One of skill in the art would recognize that the

teachings of Mack and Markowitz described above encompass molecular imaging methods."

In response to the Office Action of 12/13/06, Applicant argues that Mack et al fails to teach "...abnormal cell proliferation is indicated when the level of expression in the biological test sample is greater than said level of expression in the control test sample" (see claim 34). Applicant further argues that Mack et al does not teach or suggest the element of a comparison of transketolase like-1 (TKT-L1) expression in normal versus abnormal cell proliferations. Applicant further argues that Mack et al does not teach TKTL-1 to be overexpressed in cancer tissues compared to normal healthy colon tissue. Applicant states that Mack et al teaches TKT-L1 is underexpressed in MetC as compared to PrimeC, while the current claims recite a method including comparing normal tissue (NormC) to potentially cancerous tissue. Applicant further states that Mack et al does not teach a comparison indicating that expression in PrimC is higher relative to NormC (which Applicant indicates is recited in claim 34). Applicant further states that Applicant believes that paragraph 42 specifically relates to Tables 15, 21, and 22 (which do not reference TKT-L1). Applicant further argues: "Based on the Mack et al patent application TKT-L1 expression in PrimC can be higher, equal to, or lower, compared to NormC. Mack et al. omits a NormC to Prim C comparison, even though it is well-known in the art that PrimC are the pre-stage to MetC, and would be indicative of abnormal cell proliferation, as claimed in the present application". Applicant further states: "...the claimed comparison of normal to cancerous cells, as disclosed in Mack et al. is at best a disclosure of the genus of

expressed genes, and not a teaching of the use of the species of transketolase-like 1. A genus does not always anticipate a claim to a species within a genus. However, when the species is clearly named, the species claim is anticipated....In Mack et al., the species is not clearly named for the use the Examiner alleges it taught". Applicant further states that Mack et al fails to teach the specific comparison of sequences homologous to SEQ ID NO:1 (TKT-L1) in normal cells as compared to in potentially abnormal test cells. Applicant further states that Mack et al fails to teach that a greater level of expression of sequences having homology to SEQ ID NO:1 is indicative of abnormal cell proliferation. Applicant further presents numerous arguments directed towards an obviousness-type rejection.

The amendments to the claims and the arguments in the Response of 3/13/07 have been carefully considered, but are not deemed persuasive. In regards to the argument that Mack et al fails to teach "...abnormal cell proliferation is indicated when the level of expression in the biological test sample is greater than said level of expression in the control test sample", it is noted that claim 34 is not drawn to detecting abnormal cell proliferation. Rather, claim 34 is drawn to detecting disorders characterized by abnormal cell proliferation. Mack et al clearly teaches a diagnosis of *a disorder characterized by abnormal cell proliferation* is indicated when the level of expression in the biological test sample is greater than said level of expression in the control test sample (see Table 17 and paragraphs 42-43, and 194-195, in particular). One of skill in the art would recognize that colon cancer and metastasis of colon cancer are disorders characterized by abnormal cell proliferation (also see paragraph 34 of

Mack et al). As exemplified in Table 17, Mack et al clearly teaches a diagnosis of colon cancer when the level of expression in the biological test sample (PrimC) is greater than said level of expression in the control test sample (MetC).

In regards to the argument that that Mack et al does not teach or suggest the element of a comparison of transketolase like-1 (TKT-L1) expression in normal versus abnormal cell proliferations, "normal versus abnormal cell proliferations" are not limitations recited in the pending claims.

In regards to the argument that Mack et al does not teach TKTL-1 to be overexpressed in cancer tissues compared to normal healthy colon tissue and that Mack et al does not teach a comparison indicating that expression in PrimC is higher relative to NormC, TKTL-1 "overexpression in cancer tissues compared to normal healthy colon tissue" and "expression in PrimC is higher relative to NormC" are not limitations recited in the pending claims.

In regards to the statement that Applicant believes that paragraph 42 specifically relates to Tables 15, 21, and 22 (which do not reference TKT-L1), Mack et al teaches that the "normal" tissue taught in paragraph 42 includes both "normal" tissue from a healthy individual and non-metastatic tissue (see paragraph 43, in particular). Examples with non-metastatic tissue as "normal" tissue are taught in Table 17, which includes TKTL-1 expression.

In regards to the following argument: "Based on the Mack et al patent application TKT-L1 expression in PrimC can be higher, equal to, or lower, compared to NormC. Mack et al. omits a NormC to Prim C comparison, even though it is well-known in the art

that PrimC are the pre-stage to MetC, and would be indicative of abnormal cell proliferation, as claimed in the present application", this argument is directed to limitations not recited in the claims. The claims do not recite a "NormC to Prim C comparison" or methods of detecting "abnormal cell proliferation".

In regards to the following argument: ""...the claimed comparison of normal to cancerous cells, as disclosed in Mack et al. is at best a disclosure of the genus of expressed genes, and not a teaching of the use of the species of transketolase-like 1. A genus does not always anticipate a claim to a species within a genus. However, when the species is clearly named, the species claim is anticipated....In Mack et al., the species is not clearly named for the use the Examiner alleges it taught", this argument is directed to limitations not recited in the claims. The claims do not recite a "comparison of normal to cancerous cells". Further, the species of TKT-L1 is clearly taught, as it is clearly taught in Table 17. The genes listed in Table 17 are not a "genus"; rather, the genes listed in Table 17 are "species" taught in the methods of Mack et al. It is further noted that the species taught in Table 17, including TKT-L1, are clearly taught as species to be used in methods taught in paragraphs 42-43 and 194-195 of Mack et al.

In regards to the argument that Mack et al fails to teach the specific comparison of sequences homologous to SEQ ID NO:1 (TKT-L1) in normal cells as compared to in potentially abnormal test cells, this argument is directed to limitations not recited in the claims. The claims are not drawn to a comparison between "normal cells" and "potentially abnormal test cells". Further, as evidenced by Kaser (US 2003/0108871 A1,

6/12/03), sequences homologous to SEQ ID NO:1 are referred to as transketolase like-1 in the art (see attached sequence comparison).

In regards to the argument that Mack et al fails to teach that a greater level of expression of sequences having homology to SEQ ID NO:1 is indicative of abnormal cell proliferation, this argument is directed to limitations not recited in the claims. The claims are not drawn to detecting abnormal cell proliferation. Further, as evidenced by Kaser (US 2003/0108871 A1, 6/12/03), sequences homologous to SEQ ID NO:1 are referred to as transketolase like-1 in the art (see attached sequence comparison).

In regards to the arguments directed towards an obviousness-type rejection, the current rejection is an anticipation rejection and not a 103-type obviousness rejection. Mack et al teaches the claimed method for the reasons stated above.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-38 and 44-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 and dependent claims 35-38 and 44-50 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission

amounting to a gap between the steps. Claim 34 recites a method of detecting disorders comprising comparing the level of expression of a gene in a biological test sample to the level of expression of said gene in a control sample wherein a diagnosis of a disorder is "indicated" when the level of expression in the biological test sample is greater than said level of expression in the control sample; however, it is unclear whether a sample from a biological test sample from a patient with said disorder has a higher level of expression than a control sample or whether a sample from a biological test sample from a patient with said disorder has a lower level of expression than a control sample. For instance, diagnosis of a disorder can be "indicated" when the level of expression in the biological test sample is greater than said level of expression in the control sample because higher expression in the biological sample indicates that said patient has the disorder. Alternatively, diagnosis of a disorder can be "indicated" when the level of expression in the biological test sample is greater than said level of expression in the control sample because a higher expression in the biological sample indicates that said patient does not have the disorder. Thus, there is a missing step involving correlating the expression level in a sample to a particular diagnosis. See MPEP § 2172.01.

Claim 49 recites the limitation "the nucleic acid probe". There is insufficient antecedent basis for this limitation in the claim. Claim 49 makes reference to a claim reciting nucleic acid probes; however, there is insufficient antecedent basis for "probe".

Claim 50 is rejected for reciting: "The method according to claim 34, wherein at least one of steps (a) and (b) comprises performing in vivo or in vitro molecular imaging". It is noted that claim 34 recites: "An in vitro method for detection of disorders...". It is unclear how in vivo molecular imaging can be an in vitro method.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-38 and 44-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of: **(1)** a genus of human transketolase like-1 genes whose complement hybridizes under stringent conditions to a sequence having at least 80% homology to SEQ ID NO:1 and **(2)** a genus of probes that hybridize under stringent conditions to a polynucleotide sequence having at least 80% homology to SEQ ID NO:1. However, the written description in this case only sets forth human transketolase like-1 polynucleotides comprising the sequence set-forth in SEQ ID NO:1 and polynucleotides that hybridize to SEQ ID NO:1. The specification does not disclose transketolase like-1 "genes" whose complement hybridizes to variants of SEQ ID NO:1 or the broad genus

of probes that hybridize under stringent conditions to a polynucleotide sequence having at least 80% homology to SEQ ID NO:1.

The prior art does not teach a genus of human transketolase like-1 genes whose complement hybridizes under stringent conditions to a sequence having at least 80% homology to SEQ ID NO:1 or a genus of probes that hybridize under stringent conditions to a polynucleotide sequence having at least 80% homology to SEQ ID NO:1.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The inventions at issue in Lilly were DNA constructs per se, the holdings of said case are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813,

at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of sequences that encompass the genera nor does it provide a description of structural features that are common to the genera. Further, in regards to genera encompassing variants, Applicant is directed to Example 13 of the Synopsis of Application of Written Description Guidelines (http://www.uspto.gov/web/menu/written.pdf), which addresses claims drawn to a genus of polypeptide variants. Example 13 states that even when a specification discloses that changes which produce variants are routinely done in the art, the specification and the claims do not provide any guidance as to precisely what changes should be made. Structural features that could distinguish the compounds of the claimed genera from others not encompassed by the genera are missing from the disclosure. No common structural attributes identify the members of the genera. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is needed. Since the disclosure fails to describe common attributes or characteristics that identify members of the genera, and because the genera are highly variant, the disclosure of SEQ ID NO:1 is insufficient to describe the genera. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genera as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genera, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 34-38 and 44-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an in vitro method for detecting colon

cancer in an individual comprising detecting in a biological sample comprising colon cancer cells obtained from said individual the level of polynucleotides comprising SEQ ID NO:1 and comparing said level to the level of polynucleotides comprising SEQ ID NO:1 in a control sample comprising normal colon cells, wherein a higher level of polynucleotides comprising SEQ ID NO:1 in said biological sample as compared to said control sample indicates that said individual has colon cancer, does not reasonably provide enablement for an in vitro method for detecting every type of disorder characterized by abnormal cell proliferation in an individual comprising detecting in any biological sample obtained from said individual and any control sample a level of expression of a transketolase like-1 gene whose complement hybridizes under stringent conditions to a sequence having at least 80% homology to SEQ ID NO:1, wherein a diagnosis of just any disorder characterized by abnormal cell proliferation is indicated, in every way, when the level of expression in the biological sample is greater than the level of expression in the control sample. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the

breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The instant claims are broadly drawn to an in vitro method for detecting every type of disorder characterized by abnormal cell proliferation in an individual comprising detecting in any biological sample obtained from said individual and any control sample a level of expression of a transketolase like-1 gene whose complement hybridizes under stringent conditions to a sequence having at least 80% homology to SEQ ID NO:1, wherein a diagnosis of just any disorder characterized by abnormal cell proliferation is indicated, in every way, when the level of expression in the biological sample is greater than the level of expression in the control sample. It is noted that since specific "stringent conditions" are not recited in the claims or defined by the specification, genes whose complements hybridize under any type of stringent conditions to any sequence having as little as 80% homology to SEQ ID NO:1 would include many genes unrelated to transketolase like-1 gene.

The prior art of Mack and Markowitz (US 2003/0235820 A1; filed 2/27/02) teaches a method for detecting colon cancer comprising detecting the presence or absence and/or the level of expression of human transketolase like-1 polynucleotide in a cell or tissue sample from an individual and assessing diagnosis, wherein the presence of overexpression is indicative of colon cancer (see Table 17 and paragraphs 42-43, in particular).

The specification teaches an in vitro method for detecting colon cancer in an individual comprising detecting in a biological sample comprising colon cancer cells

obtained from said individual the level of polynucleotides comprising SEQ ID NO:1 and comparing said level to the level of polynucleotides comprising SEQ ID NO:1 in a control sample comprising normal colon cells, wherein a higher level of polynucleotides comprising SEQ ID NO:1 in said biological sample as compared to said control sample indicates that said individual has colon cancer (Figure 1, in particular).

The state of the prior art dictates that if a molecule such as a polynucleotide comprising SEQ ID NO:1 is to be used as a surrogate for a diseased state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the polynucleotide to be used in a diagnostic manner. For example, Tockman et al (Cancer Res., 1992, 52:2711s-2718s) teach considerations necessary in bringing a cancer biomarker (intermediate end point marker) to successful application. Tockman et al teaches that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points, establish quantitative criteria for marker presence/absence and confirm marker predictive value in prospective population trials (see abstract). Early stage markers of carcinogenesis have clear biological plausibility as markers of preclinical cancer and if validated (emphasis added) can be used for population screening (p. 2713s, col 1). The reference further teaches that once selected, the sensitivity and specificity of the biomarker must be validated to a known (histology/cytology-confirmed) cancer outcome. Therefore, absent evidence of the polynucleotide's expression including the correlation to a diseased state, one of skill in

the art would not be able to predictably use the polynucleotide in any diagnostic setting without undue experimentation.

The level of unpredictability for the detection of any disease is quite high. Since neither the specification nor the prior art provide evidence of a universal association between the claimed method and every type of disorder characterized by abnormal cell proliferation, every type of sample, and expression of just any gene whose complement hybridizes under stringent conditions to a sequence having at least 80% homology to SEQ ID NO:1, a practitioner wishing to practice the claimed invention would be required to provide extensive experimentation to demonstrate such an association. Such experimentation would in itself be inventive.

One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to an in vitro method for detecting every type of disorder characterized by abnormal cell proliferation in an individual comprising detecting in any biological sample obtained from said individual and any control sample a level of expression of a transketolase like-1 gene whose complement hybridizes under stringent conditions to a sequence having at least 80% homology to SEQ ID NO:1, wherein a diagnosis of just any disorder characterized by abnormal cell proliferation is indicated, in every way, when the level of expression in the biological sample is greater than the level of expression in the control sample, and Applicant has not enabled said method because it has not been shown that diagnosis of every disorder characterized by abnormal cell proliferation is predictably indicated, in every way, when the level of expression of any transketolase like-1 gene whose complement hybridizes under

stringent conditions to a sequence having at least 80% homology to SEQ ID NO:1 in just any biological sample is greater than the level of expression in just any control sample.

In view of the teachings above and the lack of guidance, workable examples and or exemplification in the specification, it would require undue experimentation by one of skill in the art to determine with any predictability, that the method would function as claimed.

New Matter

Claims 34-38 and 44-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claim 34 recites a method of detecting expression of a gene whose complement hybridizes under stringent conditions to a sequence having at least 80% homology to SEQ ID NO:1. Descriptions of methods of detecting complements of genes that hybridize under stringent conditions to a sequence having at least 80% homology to SEQ ID NO:1 are not found in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention.

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

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